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11.2

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/701,335

11/04/2003

Jose Luis Moctezuma de la Barrera

29997/061

4924

29471 7590 01/29/2007
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EXAMINER

KHOLDEBARIN, IMAN K

ART UNIT

PAPER NUMBER

3709

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/29/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/701,335

Applicant(s)

DE LA BARRERA, JOSE LUIS
MOCTEZUMA

Examiner

I Kenneth Kholdebarin

Art Unit

3709

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/17/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 1-3 and 5-18 have been renumbered 1-17.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first, second, third and the fourth circuit where cited in claim 1 line 7, 9, 12 and 14 respectively must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must

be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 6, 7, 16 and 17 is objected to because of the following informalities:

Claim 6, 7, 16 and 17 line 2: "kinematic" should be -- kinematics --.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 10-17 are rejected under 35 U.S.C. 102 (e) as being anticipated by Quaid (US 2004/0106916).

Re Claim 10: Quaid discloses a method for registering two dimensional image data to intra-operatively digitized land mars comprising the steps of importing the two dimensional image data (S1 / Fig. 13) for the joint into memory of a surgical navigation system (10) capable of determining the position and orientation of an object within a working volume wherein the surgical navigation system includes a display (30) a central processing unit and storage (all included in computer system (10) [See paragraph 0037]; performing an anatomical survey of the joint and associate limb (step 142 / Fig. 3A) [See paragraph 0061]; digitizing selected landmarks based on the anatomical survey (S3) [See paragraph 0054]; determining a mechanical axis for the limb based on the digitized landmarks registering the two dimensional image data to the mechanical axis and displaying the registered image data on the display (30) [See paragraph 0045]; guiding a cutting jig into position within the knee joint using the surgical navigation system based on the landmarks [step 148, See paragraph 0067].

Re Claim 11: Quaid disclose the displaying of the position of the cutting jig / surgical device (212) on the display (30) relative to the registered two dimensional image data [See paragraph 0067].

Re Claim 12: Quaid discloses the displaying of a modified image (through the system (10) which includes the display (30) for the image data) based on the two dimensional image data showing a resection of a bone within the joint [See paragraph 0112].

Re Claim 13 and 14: Quaid discloses the method of obtaining two dimensional image data to be obtained pre-operatively and intra- operatively. (Quaid considers monitoring the body part under the surgery) [See paragraph 0004].

Re Claim 15: Quaid discloses the performing an initial kinematics assessment of the joint (step 708 applying block 2504-2506) [See paragraph 0162 and 0152].

Re Claim 16 and 17: Quaid discloses the method of registering the image data to the digitized landmarks and the kinematics assessment [See paragraph 0054 and 0081].

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable **in view of** Quaid (2004/0106916).

Re Claim 1: Quaid discloses a system (10) for registering two dimensional image data to intra-operatively digitized landmarks where a surgical navigation system /modual navigation of computer (36) system capable of determining a position and an orientation of an object within a working volume, including a central processing unit / processor of computer (36), a display (30) a memory unit and a storage unit / memory and storage of computer 21 [See paragraph 0035] Quaid discloses integrated of the imaging device to the computer surgical system to import the image data [See paragraph 0042].

Further Quaid discloses the system (10) of the navigation surgical device capable of performing an intra-operative anatomical survey of the joint and associated limb to digitize selected landmarks and determine a mechanical axis [See paragraph 0054]

Quaid discloses the system (10) with navigation system to register the two dimensional image data of patient to the mechanical axis and display (30) the registered two dimensional image data on the display [See Paragraph 0004]

Quaid discloses the system (10) with the help of haptic device can be used to guide the user in removing the diseased bone and guiding a cutting jig into position within the joint based on the landmarks wherein the position and orientation of the cutting jig / (surgical device 112) can be tracked by the surgical navigation system [See Paragraph 0056 and 0057].

Although Quaid fails to specifically disclose four separate circuits within one system, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have one system with one or different number of circuit, in order to assist the surgeons in joint

replacement surgery and particularly knee replacement surgery by using a surgical navigation system.

Re Claim 2: Quaid disclose a display (30) of system (10) to displays the position of cutting jig / surgical device (112) on the display relative to the registered two dimensional image data [See Fig. 12, and paragraph 0058].

Although Quaid fails to specifically disclose fourth circuit, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have one system with one or different number of circuit, in order to display the position of cutting jig or any relevant surgical device to assist the surgeons in joint replacement to identify the location of operation.

Re Claim 3: Quaid discloses the display of image based on the registered image data showing a resection plane of a bone within the joint. (In orthopedic application with the help of haptic device (30)) [See paragraph 0109].

Although Quaid fails to specifically disclose a fourth circuit, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have one system with one or different number of circuit, in order to display an image based on the registered image data showing a resection plane in order to guide the surgeon in the bone cutting operation, the skill level of the surgeon is less critical.

Re Claim 4: Quaid discloses the image data is obtained intra-operatively (as part of the utilities of system (10)) [See paragraph 0004].

Re Claim 5: Quaid discloses a system with haptic device (113) that performs an initial kinematics assessment of the joint [See paragraph 0053].

Although Quaid fails to specifically disclose a fifth circuit within the system, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have one system with one or different number of circuit, in order to perform initial kinematics assessment in order create the input for to coordinate transformation processor to assist the surgeon to find the coordinate of the joint.

Re Claim 6: Quaid discloses the software module to register the image data to the digitized landmarks, and to the kinematics assessment. Quaid explains that the registration may include any known registration technique, such as image to image or image to physical space [See paragraph 0043].

Although Quaid fails to specifically disclose a third circuit within the system, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have one system with one or different number of circuit, in order to register the image data to the landmarks for a better visualization of the landmark locations on the image displayed intra-operation.

Re Claim 7: Quaid discloses the system (10) to display of digitized landmarks along with the registered two dimensional image data on display (30) [See paragraph 0040].

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Although Quaid fails to specifically disclose a fourth circuit within the system, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have one system with one or different number of circuit, in order to display the landmarks on the image data for a better visualization of the landmark locations on the image displayed intra-operation.

Re Claim 8: Quaid discusses about applying of plane resection to assist the surgeons with varying degrees of skill and experience to be able to perform accurate, repeatable bone resections.

Although Quaid fails to disclose or fairly suggest a fourth circuit to displays a proposed resection plane on the registered two dimensional image data, it would have been obvious to one of ordinary skill in the art at the time the invention was made to display the resection plane on a registered image, in order to clearly define the excision of all or part of a bone and assist the orthopedic surgeons.

Re Claim 9: Quaid discloses that the system (10) via the display (30) is able to displays the varus / valgus data and extension flexion data in display (30) [See paragraph 0113].

Although Quaid fails to specifically disclose a fourth circuit within the system, it would have been obvious to one of ordinary skill in the art at the time the invention was made to display varus/ valgus angle, and flexion angle in order to help the user implanting a first implant on a first bone.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicants disclosure. Hunter discloses Six degree of freedom alignment display for medical procedures ; Abovitz discloses System and method for intra-operative haptic planning of a medical procedure; Carson discloses Surgical navigation systems and processes for high tibial osteotomy ; Krause discloses Computer-aided orthopedic surgery ; Kande discloses Computer aided surgical plan provision method for orthopedic surgery, involves generating final surgical plan based on generated pre-surgical plan and intra-operative feedback obtained from surgeon; Chader discloses imaging system having interactive medical instruments and methods; Bucholz discloses system for indicating the position of a surgical probe within a head on an image of the head.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to I Kenneth Kholdebarin whose telephone number is 571-270-1347. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jong-Suk (James) Lee can be reached on 571-272-7044: The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IKK
01/17/2007



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SUPERVISORY PATENT EXAMINER